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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/628,033 | 07/25/2003 | Paul Harold Bryson | 66140P029 | 3354 |

8791 7590 01/23/2008

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| EXAMINER | |
|---|---|
| YU, GINA C | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1617 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 01/23/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/628,033 | BRYSON ET AL. | |
| | Examiner | Art Unit | |
| | Gina C. Yu | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *13 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1 and 4-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Receipt is acknowledged of response filed on November 13, 2007. Claims 1, 4, 6-15 are pending. Claim rejections made under 35 U.S.C. § 103 (a), as indicated in the previous Office action dated August 10, 2007, are withdrawn in view of the applicants' amendment. New rejections are made to address the amended claims.

### *Claim Rejections - 35 USC § 103*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 1, 4, 7, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke et al. (US 4818523).**

Clarke et al. disclose a hair-conditioning composition comprising 0.50 % of a glycol (propylene glycol), 1 % of a silicone (cyclomethicone), 1 % of a quaternium (dodecyl trimethyl ammonium chloride), and a polymeric thickener (hydroxyethylcellulose). See Example 2; col. 9, lines 20 – 52; instant claims 1 and 7

The composition also comprises Germaben II, which is a mixture of parabens. See instant claim 13. The reference teaches making the composition in the range of pH 3-4. See col. 9, lines 20-51. See instant claims 1 and 4.

Regarding the new limitation "free of an alpha-hydroxy acid", although Clarke teaches in col. 8, lines 44 – 48, "[s]uitable acids which may be used when needed are citric acid and the like," the reference still renders the present invention obvious because Example 2 does not indicate any content of the acid in the formulation, and also because the passage in the quotation suggests using the acid only when needed.

Furthermore, the mere exclusion of an alpha-hydroxy acid in the present composition is not viewed nonobvious since the reference suggests also using acids other than citric acid, which can be any type of traditional buffering acids other than alpha-hydroxy acids.

The reference teaches that cyclic or linear silicone is used in amount of about 0.5 – 1.5 %, which is within obvious range of the lower limitation of the claimed range. See col. 6, lines 41 –58. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this case, there is no criticality seen in modifying the weight amount of silicone from 1.5 % to 2 %. Given the teaching of the prior art, the skilled artisan would have discovered the optimum weight amount for the silicone by routine experimentations.

**Claims 1, 4, 6-9, 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Espinoza (US 6709773 B2) in view of Flick (Cosmetic and Toiletry Formulations, 1997, 2nd Ed., Vol. 6).**

Espinoza teaches a multivesicular emulsion drug delivery composition. The reference teaches using a mixture of behenyltrimonium methosulfate and cetearyl alcohol as an emulsifier. See col. 2, line 61 – col. 3, line 60. See instant claims 9, 11, and 14. A sample sunscreen lotion formulation contains 3 % of Incroquat Behenyl TMS

(a blend of behetrimonium methosulfate and cetearyl alcohol), 4 % of glycerin, 66.2 % of water, and avocado oil (a vegetable oil). See instant claims 1, 6, 9, 11-13. Glycols including glycerin, propylene glycol, and butylene glycol are also taught as solvent and moisturizers in col. 5, lines 3-10 and lines 37 – 55, and used in sample formulations. The reference also teaches that moisturizers dimethicone and cyclomethicone are used in 1 % and 5 %, respectively, by weight of a composition. See Self-tanning cream in col. 6, line 62 – col. 7, line 9; col. 5, lines 38 – 56. The specific examples of the reference employ cetyl alcohol and stearyl alcohol which function as viscosity modifier, and the reference further disclose polymeric, viscosity modulators such as hydroxyethylcellulose, xanthan gum, and veegum. See col. 4, line 55 – col. 5, line 2. See instant claims 1, 6, and 15. The claimed method of topically applying the topical compositions by rubbing and leaving the composition on the skin is an obvious use of the topical product. See instant claim 15. Thus, Espinoza would have obviously motivated one of ordinary skill in the art at the time of the present invention to modify the teachings of the references and make and use a topical composition comprising a glycol, a silicone, a quaternium, and a polymer viscosity modulator within the weight amount as presently claimed.

Although Espinoza does not specifically teach the pH of the exemplified compositions, the reference indicates that hydroxyethylcellulose is compatible with strontium nitrate and is stable at pH values around 3, which implies the suitable pH range of the prior art compositions. See col. 5, lines 1-2; instant claims 1, 4, and 15.

Regarding the new limitation "free of an alpha-hydroxy acid", although Espinoza mentions citric acid as a pH adjuster, the reference still renders the present invention obvious because citric acid here is mentioned only as one example of old and well known pH adjusting agents that can be used by a skilled artisan. Espinoza teaches using "other suitable ingredients" well known in cosmetic art, and does not in any way suggest that an alpha-hydroxy acid is a required element to make a prior art composition.

For example, Flick teaches that phosphoric acid and citric acid are interchangeably used to adjust pH of a cosmetic composition. See p. 37, Shower Gel with Mbaruti Oil, Mixing Instruction.

It would have been obvious to the skilled artisan to modify the teachings of Espinoza by adjusting the pH of the compositions with a conventional pH adjusting agent other than citric acid, such as phosphoric acid, as motivated by Flick, because the latter teaches that the art-recognized functional equivalency of the buffering acids. The skilled artisan would have had a reasonable expectation of successfully producing a similar acidic topical composition suitable for cosmetic use without using an alpha hydroxy acid.

**Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Espinoza and Flick as applied to claims 1, 4, 6-9, 13-15 as above, and further in view of Cosmetics Additives (1991).**

Espinoza and Flick fail to teach the viscosity modulators of instant claim 10.

Cosmetics Additives teaches that propylene glycol dicaprylate/dicaprate is a luxuriant emollient, moisturizers with excellent lubricity and non-oily skin deposition for creams and lotions. See p. 415; instant claim 10.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the composition of the combined references by adding propylene glycol dicaprylate/dicaprate as motivated by Cosmetics Additives because the latter teaches that it provides luxuriant emolliency and non-oily skin deposition of the cream composition. The skilled artisan would have had a reasonable expectation of successfully producing a stable skin cream composition with enhanced emolliency and skin feel.

***Response to Arguments***

Applicant's arguments filed on November 13, 2007 have been fully considered but they are unpersuasive or moot in view of the new grounds of rejection as discussed above.

Applicants assert, "the claimed composition achieves a low pH in the absence of an acid." However, the argument is not commensurate with the scope of the claim because an alpha hydroxy acid is only one type of possible acidic buffering agents in cosmetic art. As discussed in the rejections above, skilled artisans would have been motivated to use conventional buffering agents other than alpha hydroxy acids to achieve the required pH level of the prior art compositions.

Regarding the Clarke reference, examiner respectfully disagrees with applicants' statement, "Clarke discloses a composition having a pH in the range of 3-4 which includes an alpha-hydroxy acid and/or citric acid". As discussed in the rejection above, the exemplified compositions of Clarke do not show an alpha-hydroxy acid and/or citric acid in the formulation. Nor is there any teaching or suggestion in the reference to lead a routineer to adjust the pH of the composition by using an alpha-hydroxy acid only.

Applicants' arguments with respect to the obviousness rejection made in view of the alpha-hydroxy acid cream composition of Espinoza are moot in view of the new grounds of rejection.

Regarding the obviousness rejection on claim 10, applicants assert that the rejection fails to point to a portion of Cosmetic Additives (Flick2) that is relevant to the rejection. It is reiterated that the Cosmetic Additives discloses the advantageous emollient/moisturizing properties of propylene glycol dicaprylate/dicaprate, "a polymeric viscosity modulator" of claim 10. It is thus viewed that a skilled artisan would have been motivated to employ this specific ingredient to modify the prior art composition of Espinoza/Flick to obtain the said emolliency

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-8605. The examiner can normally be reached on Monday through Friday, from 8:00AM until 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gina Yu

Gina C. Yu
Patent Examiner